CAMPBELL & FLORES LLP

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CAMPBELL & FLORES

Attorneys

Biotechnology Intellectual Property 4370 La Jolla Village Drive, Suite 700 San Diego, California 92122 Telephone: (858) 535-9001 Facsimile: (858) 535-8949 **USPTO CUSTOMER NO. 23601**

IMPORTANT NOTICE

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GROUP 1800

August 2, 2002

DATE

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that these 23 pages are

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Examiner L. Helms

Group 1642

Fax No.:

703-308-4242

FROM:

John T. Murphy

Reg. No.: 50,583

OUR DOCKET NO.: P-IX 2947

REFERENCE: Serial No.: 09/203,768

Filed: December 2, 1998

Entitled: TUMOR SPECIFIC HUMAN MONOCLONAL ANTIBODIES AND METHODS OF

Christine Grace NAME (printed)

USE

DATE:

August 2, 2002

NO. OF PAGES (Including this page); 23

SPECIAL INSTRUCTIONS:

Transmitted herewith are the following OFFICIAL documents:

- 1) Transmittal Letter with duplicate (4 pages)
- 2) Communication Enclosing Copy of Previously Filed Documents And Appointment of Associate Attorney
- 3) Copies of the following documents as originally filed by first class mail on April 5, 2002:
 - A. Response to the Advisory Action mailed January 25, 2002, and the final Office Action mailed May 3, 2002, with attached Appendix A (5 pages)
 - B. Petition for Extension of Time (1 page)
 - C. Request for Continued Examination (2 pages)
 - D. Transmittal Form PTO-1083 (2 pages)
 - E. Check no. 028425 in the amount of \$830.00 (1 page)
 - F. Postcard (1 page)
- 4) Copies of the following documents as originally filed by first class mail on April 10, 2002:
 - A. Appointment of Associate Attorney with First Class Mail Certification (2 pages)
 - B. Transmittal Letter (1 page)
 - C. Postcard (1 page)

Please contact Christine Grace at (858) 535-9001 if you DO NOT receive all pages.

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U.S. Mail	Express Mail	Will Not Follow XX

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TR	ANSMITTAL LETTER		DOCKET NUMBER: P-IX 2947			
SERIAL NO: 09/203,768	FILING DATE: December 2, 1998	EXAMINER: L. Helms		GROUP ART UNIT: 1642		
INVENTION: T	TUMOR SPECIFIC HUMAN MUSE	ONOCL	ONAL AN	TIBODIES AND		

TO COMMISSIONER FOR PATENTS

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that these 23 pages are being facsimile transmitted to the Patent and Trademark Office on the date shown below:

Christine Grace
NAME (printed)

Christian Janes August 2, 2002
Signature DATE

Transmitted herewith are the following documents in connection with the above-identified application:

- Communication Enclosing Copy of Previously Filed Documents
- Copy of documents originally filed with the United States Patent and Trademark Office by first class mail on April 5, 2002, including:
 - A. Response to the Advisory Action mailed January 25, 2002, and the final Office Action mailed May 3, 2002, with attached Appendix A;
 - B. Petition for Extension of Time
 - C. Request for Continued Examination;
 - D. Transmittal form PTO-1083;
 - E. Check No. 028425 in the amount of \$830.00; and
 - F. Submitted postcard
- 3. Copy of documents originally filed with the United States Patent and Trademark Office by first class mail on April 10, 2002, including:
 - A. Appointment of Associate Attorney;
 - B. Transmittal Letter; and
 - C. Submitted postcard
- Please charge my Deposit Account No. 03-0370 the amount of \$_____ A duplicate copy of this sheet is enclosed.
- X The Commissioner is hereby authorized to charge payment of any fees associated with this communication or credit any overpayment to Deposit Account No. 03-0370. A duplicate copy of this sheet is enclosed.

Inventors: Watkins and Huse

Serial No.: 09/203,768

Filed:

December 2, 1998

Page 2

The Commissioner is hereby authorized to charge to Deposit Account No. 03-0370 any fees under 37 CFR 1.17 which may be required under 37 CFR 1.136(a)(3) for an extension of time in any concurrent or future reply requiring a petition for extension of time. A duplicate copy of this sheet is

Respectfully submitted,

John T. Murphy Registration No. 50,583 CAMPBELL & FLORES LLP

4370 La Jolla Village Drive

7th Floor

San Diego, California 92122 858-535-9001

USPTO CUSTOMER NO. 23601

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OFFICIAL

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PATENT

Our Docket: P-IX 2947

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Watkins and Huse

Serial No: 09/203,768

Filed: December 2, 1998

For: TUMOR SPECIFIC HUMAN MONOCLONAL ANTIBODIES

AND METHODS OF USE

Commissioner for Patents Washington, D.C. 20231

Examiner: L. Helms

Group Art Unit: 1642

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that these 23 pages are being facsimile transmitted to the Patent and Trademark Office on the date shown below:

Christine Grace
NAME (printed)

prestre OLOCO August 2, 2002

COMMUNICATION ENCLOSING COPY OF PREVIOUSLY FILED DOCUMENTS

Pursuant to the "NOTE" included in the Office Action mailed June 20, 2002, applicants attach herewith complete and accurate copies of the documents that were originally filed with the United States Patent and Trademark Office (USPTO) by first class mail on April 5, 2002 and April 10, 2002, in connection with the above-identified application. Applicants respectfully request that the USPTO add the original mailroom date to the attached copies and that the USPTO use the attached copies as the permanent USPTO record in place of the copies made by the USPTO of the filings submitted on April 5, 2002, and April 10, 2002, in connection with the above-identified application.

In regard to the filing submitted to the United States
Patent and Trademark Office by first class mail on April 5, 2002,
the attached documents include copies of the response to Advisory

Watkins and Huse

• Serial No.:

09/203,768

Filed:

December 2, 1998

Page 2

Action mailed January 25, 2002, and the final Office Action mailed May 3, 2001, with attached Appendix A; Petition for Extension of Time; Request for Continued Examination; Transmittal form PTO-1083; check no. 028425 in the amount of \$830.00; and the submitted postcard.

In regard to the filing submitted to the United States
Patent and Trademark Office by first class mail on April 10,
2002, the attached documents include copies of the Appointment of
Associate Attorney; Transmittal Letter; and the submitted
postcard.

No Fee is deemed necessary in connection with the filing of this Communication. However if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-0370.

Should there be any questions the Examiner is invited to call the undersigned agent or Cathryn Campbell.

Respectfully submitted,

August 2, 2002

Date

John T. Murpky

Registration No. 50,583

Telephone No. (858) 535-9001 Facsimile No. (858) 535-8949

CAMPBELL & FLORES LLP 4370 La Jolla Village Drive 7th Floor San Diego, California 92122 USPTO CUSTOMER NO. 23601 Avery Lar Index & Postcard #5389

Please acknowledge receipt of the accompanying:

Response to Advisory Action mailed January 25, 2002 and final Office Action mailed May 3, 2001, with attached Appendix A

Other Request for Continued Examination (in duplicate)

☑ Transmittal form PTO-1083 (in duplicate)

Petition for 3 month Extension of Time (in duplicate)
Applicant's Name Watkins and Huse
Serial Number 09/203,768 Filing Date 12/02/199
Examiner's Name L. Helms Group Art Unit 1642

Title TUMOR SPECIFIC HUMAN MONOCLONAL ANTIBODIES AND METHODS OF USE

Certificate of Mailing - 1st Class Date Mailed: 04/05/2002
Our Docket No.: P-IX 2947 Date Due: 04/05/2002
Client APPLIED MOLECULAR EVOLUTION, INC.

Attorney/Secretary DAG/JTM/kcc

Place your receiving date stamp hereon and return this card.

FORM UA Amend/Resp

AMENDMENT TRANSMITTAL LETTER DOCKET NUMBER:
P-IX 2947

SERIAL NO: FILING DATE: EXAMINER: GROUP ART UNIT:
09/203,768 December 2, 1998 L. Helms 1642

INVENTION: TUMOR SPECIFIC HUMAN MONOCLONAL ANTIBODIES AND METHODS OF USE

TO COMMISSIONER FOR PATENTS ATTN: Box RCE

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Attention Box RCE, Washington,

Patients, Attention Box RCE, Washington, D.C., 70231 on April 5, 2002.

By:
John T. Murphy, Reg. No. 50,583

April 5, 2002
Date of Signature

Transmitted herewith is a Request for Continued Examination in response to the Office Action mailed January 25, 2002, and the final Office Action mailed May 3, 2001, (in duplicate) in the above-identified application.

- X Small Entity status of this application has been established under 37 CFR 1.27.
- <u>X</u> Petition for Extension of Time is enclosed (in duplicate).
- X Response to Advisory Action mailed January 25, 2002, and the final Office Action mailed May 3, 2001, with attached Appendix A is enclosed.
- _X_ No additional claims fee is required.

CLAIMS AS AMENDED

	NUMBER AFTER	AFTER	FICHEST NUMBER	ŀ	NUMBER OF EXTRA CLAIMS PRESENTED		RATE		FEE		
	MENT -		PREVIOUSLY PAID FOR				SMALL ENTITY	OTHER ENTITY		SMALL ENTITY	OTHER ENTITY
Total Claims	48	-	48	-	0	×	\$9	\$18	_	\$0	ş
INDEPEN- DENT CLAIMS	14	-	14		a	x	\$42	\$84	=	\$0	ş
FIRST PRESENTAT MULTIPLE DEPENDENT			YES		х ио		\$140	\$280	=	\$0	\$
							TOTAL ADDITION	JAL FEE		\$0	ş

- If the "HIGHEST NUMBER PREVIOUSLY PAID FOR" is less than 20, write "20" in this space.
- •• If the "HIGHEST NUMBER PREVIOUSLY PAID FOR" is less than 3, write "3" in this space.
- *** If the difference between the "NUMBER AFTER AMENDMENT" and the "RIGHEST NUMBER PREVIOUSLY PAID FOR" is less than 0, write "0" in the space.
- Please charge my Deposit Account No. 03-0370 the amount of \$_____ A duplicate copy of this sheet is enclosed.

Watkins and Huse

Serial No .:

09/203,768

Filed:

December 2, 1998

Page 2

X A check in the amount of \$830.00 is enclosed, \$370.00 of which covers the request for continued examination fee under 37 C.F.R. § 1.17(e) and \$460.00 of which covers the fee for a three-month extension of time.

X The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 03-0370. A duplicate copy of this sheet is enclosed.

X Any additional filing fees required under 37 C.F.R. 1.16.

Any patent application processing fees under 37 C.F.R. 1.17.

The Commissioner is hereby authorized to charge to Deposit Account No. 03-0370 any fees under 37 CFR 1.17 which may be required under 37 CFR 1.136(a)(3) for an extension of time in any concurrent or future reply requiring a petition for extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

April 5, 2002

Date

John T. Murphy

Régistration No. 50,583 CAMPBELL & FLORES LLP

4370 La Jolla Village Drive

7th Floor

San Diego, California 92122

858-535-9001

USPTO CUSTOMER NO. 23601

Ø 011

028425

Commissioner for Patents \$830.00/ RCE fee and 3 mo. EOT/ P-IX 2947 4/5/02

CAMPBELL & FLORES LLP

OPERATING ACCOUNT (858) 535-9001 4970 LA JOLLA VILLAGE DR., 7TH FLOOR SAN DIEGO, CA 92122 US BANK

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eight hundred thirty and 00/100

4/5/02 DATE

AMOUNT 830.00

028425

TO THE **ORDER**

OF

Commissioner for Patents

#O 284 25# #122235821#165600453212#

CAMPBELL & FLORES LLP

028425

PATENT

Our Docket: P-IX 2947

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Watkins and Huse

Serial No: 09/203,768

Filed: December 2, 1998

For: TUMOR SPECIFIC HUMAN MONOCLONAL ANTIBODIES AND METHODS OF USE

ATTN: Box RCE

Commissioner for Patents Washington, D.C.

Group Art Unit: 1642

Examiner: L. Helms

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Attention Box RCE, Washington, A02B1. D.C., April 8, 2002.

Joh eg. No. 50,583

Date of Signature

PETITION FOR EXTENSION OF TIME

Applicants hereby petition for a three-month extension of time to respond to the Official Actions mailed on January 25, 2002 and May 3, 2001.

A check in the amount of \$830.00 is enclosed, \$370.00 of which covers the request for continued examination fee under 37 C.F.R. § 1.17(e) and \$460.00 of which covers the fee for the three-month extension of time.

The Commissioner is hereby authorized to charge payment of any additional fees associated with the filing submitted herewith or credit any overpayment to Deposit Account No. 03-0370. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

Date:___ 2002 April 5,

John T. Murph

Redistration No. 50,583 Telephone: (858) 535-9001 Facsimile: (858) 535-8949

CAMPBELL & FLORES LLP 4370 La Jolla Village Drive 7th Floor San Diego, California 92122 USPTO CUSTOMER NO. 23601

PATENT

Our Docket: P-IX 2947

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Watkins and Huse

Serial No.: 09/203,768

Filed: December 2, 1998

For: TUMOR SPECIFIC HUMAN

MONOCLONAL ANTIBODIES AND METHODS OF USE

Box RCE

Commissioner for Patents Washington, D.C. 20231

Group Art Unit: 1642

Examiner: L. Helms

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D.C., 20231, April 5, 2002.

John T. Murphy Reg. No. 50,583

Date of Signature

REQUEST FOR CONTINUED EXAMINATION

This is a request for continued examination of the above-identified application. 37 C.F.R. § 1.114.

At least one of the following submissions is being filed herewith:

X Amendment or Response
Declaration or Affidavit
Information Disclosure Statement

A check in the amount of \$830.00 is being filed herewith, \$370.00 of which covers the request for continued examination fee under 37 C.F.R. § 1.17(e) and \$460.00 of which covers the fee for a three-month extension of time.

Watkins and Huse

Serial No.:

09/203,768

Filed: Page 2

December 2, 1998

The Director is hereby authorized to charge payment or credit any overpayment to Deposit Account No. 03-0370 for any of the following fees: additional filing fees under 37 C.F.R. § 1.16, patent application processing fees under 37 C.F.R. § 1.17, or any fees under 37 C.F.R. § 1.17 that may be required under 37 C.F.R. § 1.136(a)(3) for an extension of time in any concurrent or future reply requiring a petition for extension of time. A duplicate copy of this sheet is enclosed for this purpose.

Accordingly, the Applicants respectfully request withdrawal of the finality of the outstanding office action, and consideration of the submission filed herewith. The Examiner is invited to call the undersigned agent or Cathryn Campbell with any questions.

Respectfully submitted,

April 5, 2002

Date

John T. Murphy

Redistration No. 50,583

Telephone No. (858) 535-9001 Facsimile No. (858) 535-8949

CAMPBELL & FLORES LLP 4370 La Jolla Village Drive 7th Floor San Diego, California 92122 USPTO CUSTOMER NO. 23601

PATENT

Our Docket: P-IX 2947

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Watkins and Huse

Serial No.: 09/203,768

Filed: December 2, 1998

For: TUMOR SPECIFIC HUMAN

MONOCLONAL ANTIBODIES AND METHODS OF USE

Box RCE

Commissioner for Patents Washington, D.C. 20231

Group Art Unit: 1642

Examiner: L. Helms

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John T. Murphy, Reg. No. 50,583

Date of Signature

RESPONSE TO OFFICE ACTION

Responsive to the Advisory Action mailed

January 25, 2002, and the final Office Action mailed May 3, 2001,
entry of the following amendments and remarks is respectfully
requested.

AMENDMENTS

1. (Thrice amended) A human monoclonal antibody or functional fragment thereof, comprising the amino acid sequence of SEQ ID NO:2, or having a conservative substitution of an amino acid thereof, and the amino acid sequence of SEQ ID NO:4, or having a conservative substitution of an amino acid thereof, wherein said antibody or functional fragment thereof binds a neoplastic cell or antigen thereof.

Watkins and Huse

Serial No.:

09/203,768

Filed: Page 2 December 2, 1998

functional fragment thereof, comprising a heavy chain variable region having the three CDR sequences of the amino acid sequence of SEQ ID NO:2, or having a conservative substitution of an amino acid thereof, and a light chain variable region having the three CDR sequences of the amino acid sequence of SEQ ID NO:4, or having a conservative substitution of an amino acid thereof, wherein said antibody or functional fragment thereof binds a neoplastic cell or antigen thereof.

REMARKS

Claims 1-6, 47 and 48 are pending in the above-identified application. By the present communication claims 1 and 6 have been amended. Support for the amendments can be found in the specification including, for example, on page 8, lines 1-14; page 16, lines 10-21 and page 22, line 22, through page 23, line 7. Accordingly, the amendments do not introduce new matter. Therefore, entry of the amendments is respectfully requested. A marked-up copy of the amended claims is attached hereto as Appendix A.

Rejections under 35 U.S.C. § 112, first paragraph

Applicants respectfully traverse the rejection of claims 1-6, 47 and 48, under 35 U.S.C. § 112, first paragraph, allegedly because the specification is not enabling for a VH or VL alone or a single CDR from SEQ ID NO:2 or 4. Applicants maintain, for the reasons of record, that the full scope of the

Watkins and Huse

Serial No.:

09/203,768

Filed: Page 3 December 2, 1998

claimed invention is enabled because functional fragments of antibodies, such as single CDRs and VH domains, were known in the art and the specification provides guidance commensurate with that which was known in the art to allow one skilled in the art to make and use the claimed functional fragments. Nevertheless, in order to further prosecution of this application, claims 1 and 6 have been amended. The claims as amended, are directed to a human monoclonal antibody, or fragment thereof, that contains all six of the CDR sequences contained in SEQ ID NO:2 and SEQ ID NO:4. Therefore, the rejection has been rendered moot. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph

Applicants respectfully traverse the rejection of claims 1-6, 47 and 48, under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for reciting the term "substantially." Applicants maintain, for the reasons of record, that the claims are sufficiently clear in view of the teaching and guidance provided in the specification. Nevertheless, in order to further prosecution of this application, claims 1 and 6 have been amended. The claims, as amended, no longer recite the term "substantially." Therefore, the rejection has been rendered moot. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Watkins and Huse

Serial No.:

09/203,768

Filed: Page 4 December 2, 1998

CONCLUSION

In light of the amendments and remarks herein,
Applicants submit that the claims are now in condition for
allowance and respectfully request a notice to this effect.
Should the Examiner have any questions, he is invited to call the
undersigned agent or Cathryn Campbell.

Respectfully submitted,

<u>April 5, 2002</u>

Date

John T. Murphy

Registration No. 50,583 Telephone No. (858) 535-9001

Facsimile No. (858) 535-8949

CAMPBELL & FLORES LLP 4370 La Jolla Village Drive 7th Floor San Diego, California 92122 USPTO CUSTOMER NO. 23601

Watkins and Huse

Serial No.:

09/203,768

Filed:

December 2, 1998

APPENDIX A

A marked-up version of claims showing amendments follows.

- 1. (Thrice amended) A human monoclonal antibody or functional fragment thereof, comprising [at least one Complementarity Determining Region (CDR) having substantially] the amino acid sequence of [a CDR of] SEQ ID NO:2, or having a conservative substitution of an amino acid thereof, and the amino acid sequence of SEQ ID NO:4, or having a conservative substitution of an amino acid thereof, wherein said antibody or functional fragment thereof binds a neoplastic cell or antigen thereof.
- functional fragment thereof [A CDR or functional fragment thereof], comprising a heavy chain variable region having the three CDR sequences of [substantially] the amino acid sequence [of a CDR] of SEQ ID NO:2, or having a conservative substitution of an amino acid thereof, and a light chain variable region having the three CDR sequences of the amino acid sequence of SEQ ID NO:4, or having a conservative substitution of an amino acid thereof, wherein said antibody [CDR] or functional fragment thereof binds a neoplastic cell or antigen thereof.

FORM UA Amend/Resp

_	ease acknowledge receipt of the accompanying:	
⊗	Other Appointment of Associate Attorney Transmittal (in duplicate) Petition for month Extension of Time (in duplicate)	
•	Serial Number 09/203,768 Filing Date 12/02/1999	
	Examiner's Name L. Helms Group Art Unit 1642 Title TUMOR SPECIFIC HUMAN MONOCLONAL ANTIBODIES AND METHODS OF USE	
(Fee \$Enclosed	

Index & Postcard #5389

TR	ANSMITTAL LETTER	DOCKET NUMBER: P-IX 2947		
SERIAL NO: 09/203,768	FILING DATE: December 2, 1998	EXAMINE L. Helm		
INVENTION: T METHODS OF U		N MONOCLO	ONAL ANTIBODIES AND	

TO COMMISSIONER FOR PATENTS

I horeby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C., 20231 on April 10, 2002.

y: John T. Murphy. Reg. No. 50,583

Date of Signature

Transmitted herewith are the following documents in connection with the above-identified application:

- 1. Appointment of Associate Attorney
- Please charge my Deposit Account No. 03-0370 the amount of S_____. A duplicate copy of this sheet is enclosed.
- X The Commissioner is hereby authorized to charge payment of any fees associated with this communication or credit any overpayment to Deposit Account No. 03-0370. A duplicate copy of this sheet is enclosed.
- X The Commissioner is hereby authorized to charge to Deposit Account No. 03-0370 any fees under 37 CFR 1.17 which may be required under 37 CFR 1.136(a)(3) for an extension of time in any concurrent or future reply requiring a petition for extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

April 10, 2002

Date

John T. Murphy

Registration No. 50,583

CAMPBELL & FLORES LLP

4370 La Jolla Village Drive

7th Floor

San Diego, California 92122

858-535-9001

USPTO CUSTOMER NO. 23601

Appointment of Associate Attorney Attorney Docket No.: P-IX 2947 Serial No.: 09/203,768

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Bv

John T. Murphy, Reg. No. 50,583

April 10, 2002

Date of Signature

PATENT Our Docket: P-IX 2947

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
Watkins and Huse

Serial No: 09/203,768

Filed: December 2, 1998

For: TUMOR SPECIFIC HUMAN
MONOCLONAL ANTIBODIES AND
METHODS OF USE

)

Commissioner for Patents Washington, D.C. 20231

APPOINTMENT OF ASSOCIATE ATTORNEY

I am attorney of record in the above-referenced patent application and, pursuant to 37 C.F.R. 1.34b, I hereby appoint David A. Gay, Registration No. 39,200, Calvin A. Fan, Registration No. 38,444, Andrea L. Gashler, Registration No. 41,029, James J. Wong, Registration No. 34,949, Deborah L. Cadena, Registration No. 44,048, Melanie K. Webster, Registration No. 45,201, Astrid R. Spain, Registration No. 47,956, Kimberly J. Prior, Registration No. 41,483, John T. Murphy, Registration No. 50,583, and Pamela M. Guy, Registration No. 51,228, as associate attorneys of record to prosecute this application as well as any continuation and divisional applications and to transact all business in the Patent and Trademark Office in connection therewith.

Respectfully submitted,

Date: April 9, 2002

Cathryn Campbell

Registration No. 31,815 Telephone: (858) 535-9001 Facsimile: (858) 535-8949

CAMPBELL & FLORES LLP 4370 La Jolla Village Drive 7th Floor San Diego, California 92122 USPTO CUSTOMER NO. 23601